IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

PETER MARIO GOICO, **Plaintiff,** **v.** **UNITED STATES FOOD AND DRUG ADMINISTRATION and STEPHEN M. HAHN, COMMISSIONER OF FOOD AND DRUGS,** **Defendants.**	**Case No. 20-1248-JAR-KGG**

MEMORANDUM AND ORDER

Plaintiff Peter Mario Goico brings this action *pro se* against Defendants, the U.S. Food and Drug Administration and its Commissioner, Stephen M. Hahn (collectively, the "FDA"), alleging that the FDA is unlawfully withholding hydroxychloroquine ("HCQ") for the prevention of the SARS-CoV-2 ("COVID-19") virus. This case is now before the Court on Plaintiff's Motion to Join this Case with Case 20-1025 (Doc. 3), Plaintiff's Emergency Motion for Preliminary Injunction (Doc. 4), Plaintiff's Motion to Rebut (Doc. 20), the FDA's Motion to Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim Upon Which Relief Can Be Granted (Doc. 22), Plaintiff's Emergency Motion to Expedite Ruling on Defendants' Motion (Doc. 29), Plaintiff's Urgent Emergency Motion for Emergency TRO (Doc. 30), and Plaintiff's Motion for Permission to File a Rebuttal (Sur-Reply or Sur-Response) to [the FDA's] Reply Memorandum in Support of Defendants' Motion to Dismiss (Doc. 32). For the reasons explained in detail below, Plaintiff's motion for leave to file a sur-reply is granted, the FDA's motion to dismiss is granted, this case is dismissed, and Plaintiff's remaining motions are denied as moot.

I. Factual and Procedural History

Plaintiff is a resident of Wichita, Kansas. He filed his Complaint on September 16, 2020, alleging causes of action purportedly arising under: (1) 21 U.S.C. § 360bbb-3, which is the federal statute pursuant to which the FDA may issue an emergency use authorization ("EUA") for drugs and other FDA-regulated products; (2) the Administrative Procedure Act, 5 U.S.C. §§ 701−706; and (3) 28 U.S.C. § 1343 for the deprivation of his civil rights. In his Statement of Claim, Plaintiff contends that

> [t]he Food and Drug Administration is effectively holding me and my seventy-five year old father under illegal house arrest by withholding a drug (hydroxychloroquine) necessary to leave. They may not be using bars and guns to keep us restrained; they are using the Covid-19 virus, which can be equally deadly, especially in Kansas where Covid-19 is rapidly spreading. We live in constant danger of contracting and dying from the Covid-19. . . . This is all because the FDA is withholding a prophylaxis called hydroxychloroquine. This medication is provably safer than some over the counter drugs . . . [and] has been used for sixty-five years (with FDA approval) for malaria prevention . . . . Meanwhile, I have spoken to at least five medical professional[s] who refuse to give either of us a prescription due to it being deemed "unsafe". This declaration of "unsafe" is without any basis by the FDA while there are tests that prove it is not only safe but effective. . . .[1]

Plaintiff argues that his civil rights are being violated, seeks declaratory judgment pursuant to 28 U.S.C. §§ 2201−2202, and requests that this Court "enjoin the FDA from disallowing prophylaxis [sic] use of hydroxychloroquine and enjoin any medical authority from punishing any doctor who prescribes hydroxychloroquine as a prophylaxis for COVID-19."[2]

[1] Doc. 1 at 2−3.

[2] *Id*. at 3.

Before the FDA appeared in this case, Plaintiff filed an "Emergency Motion for Preliminary Injunction" seeking such relief.[3] Because Plaintiff titled his pleading as an "emergency" motion, the Court examined whether Plaintiff had satisfied his heavy burden in seeking a temporary restraining order ("TRO") without notice under Fed. R. Civ. P. 65(b)(1). In a September 22, 2020 Order, the Court found that Plaintiff had not met that burden because he failed to make a sufficient showing that he would suffer irreparable and immediate harm before the FDA could be heard in opposition to his motion.[4] The Court ordered the FDA to respond to Plaintiff's motion for a preliminary injunction on or before October 20, 2020.

Rather than awaiting the FDA's response to his motion for a preliminary injunction, Plaintiff filed a second "Emergency Motion for TRO."[5] The Court denied that motion on September 28, 2020, and ordered that the October 20, 2020 deadline for the FDA's response to Plaintiff's motion for a preliminary injunction would remain in effect.[6] Plaintiff then filed an "Addendum to Emergency Motion for TRO" and a "Motion to Rebut," which seeks reconsideration of the Court's denial of his second request for a TRO.[7]

On October 20, 2020, the FDA filed a motion to dismiss for lack of subject matter jurisdiction and failure to state a claim, along with its opposition to Plaintiff's motion for a preliminary injunction.[8] In its motion to dismiss, the FDA raises lack of standing and subject matter jurisdiction, which are threshold issues. On October 21, 2020, the Court issued an Order stating that because it must assure itself of its own jurisdiction before proceeding to any request

[3] Doc. 4.

[4] Doc. 6 at 3.

[5] Doc. 14.

[6] Doc. 15 at 3−4.

[7] Docs. 16, 20.

[8] Docs. 22−23.

for injunctive relief, it would decide the FDA's motion to dismiss before ruling on Plaintiff's motion for a preliminary injunction.[9]

The Court ordered Plaintiff to file both his response to the FDA's motion to dismiss and his reply in support of his motion for a preliminary injunction on or before November 10, 2020, and the FDA to file its reply in support of its motion to dismiss within fourteen days of Plaintiff's response. Plaintiff instead filed his response the same day, October 21, followed by an emergency motion to expedite the Court's ruling on the FDA's motion to dismiss, another emergency motion for a TRO, a motion for leave to file a sur-reply in opposition to the FDA's motion to dismiss, and a pleading titled "Rebuttal Evidence."[10] Ultimately, the Court need only address the FDA's motion to dismiss—and within that motion, only the FDA's standing arguments—as explained below.

II. Legal Standard

The FDA moves to dismiss this case pursuant to Fed. R. Civ. P. 12(b)(1) for lack of subject matter jurisdiction, arguing, among other things, that Plaintiff has failed to satisfy the constitutional minimum requirements of standing necessary to bring suit. As explained in greater depth below, Plaintiff's standing is properly challenged by a Rule 12(b)(1) motion "because a party's standing implicates subject matter jurisdiction."[11]

Generally, a Rule 12(b)(1) motion to dismiss for lack of subject matter jurisdiction takes one of two forms: a facial attack or a factual attack. "First, a facial attack on the complaint's allegations as to subject matter jurisdiction questions the sufficiency of the complaint. In

[9] Doc. 24.

[10] Docs. 25, 29, 32, 33.

[11] *See Unicredit Bank AG v. Jue-Thompson*, No. 12-2468-EFM, 2013 WL 6185750, at *3 (D. Kan. Nov. 26, 2013) (quoting *McCollum v. W. Elk Sch. Bd. No. 282*, No. 13-1156-JTM, 2013 WL 3967968, at *3 (D. Kan. Aug. 1, 2013)).

reviewing a facial attack on the complaint, a district court must accept the allegations in the complaint as true."[12]

> "Second, a party may go beyond allegations contained in the complaint and challenge the facts upon which subject matter jurisdiction depends. When reviewing a factual attack on subject matter jurisdiction, a district court may not presume the truthfulness of the complaint's factual allegations. A court has wide discretion to allow affidavits, other documents, and a limited evidentiary hearing to resolve disputed jurisdictional facts under Rule 12(b)(1)."[13]

In considering "a factual attack under Rule 12(b)(1), a court's reference to evidence outside the pleadings does not convert the motion into a Rule 56 [summary judgment] motion."[14] As the party seeking to invoke federal jurisdiction, Plaintiff bears the burden of proving jurisdiction as a threshold matter.[15]

Because Plaintiff proceeds *pro se*, some additional considerations frame the Court's analysis. The Court must construe Plaintiff's pleadings liberally and apply a less stringent standard than that which applies to attorneys.[16] "Nevertheless, [Plaintiff] bears 'the burden of alleging sufficient facts on which a recognized legal claim could be based.'"[17] The Court may not provide "additional factual allegations to round out a plaintiff's complaint or construct a legal

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[12] *Holt v. United States*, 46 F.3d 1000, 1002 (10th Cir. 1995) (citing *Ohio Nat'l Life Ins. Co. v. United States*, 922 F.2d 320, 325 (6th Cir. 1990)).

[13] *Id*. at 1003 (citations omitted); *see also Davis ex rel. Davis v. United States*, 343 F.3d 1282, 1296 (10th Cir. 2003).

[14] *Stuart v. Colo. Interstate Gas Co*., 271 F.3d 1221, 1225 (10th Cir. 2001) (citing *Holt*, 46 F.3d at 1003).

[15] *See, e.g., Marcus v. Kan. Dept. of Revenue*, 170 F.3d 1305, 1309 (10th Cir. 1999); *Bushnell, Inc. v. Brunton Co*., 659 F. Supp. 2d 1150, 1157 (D. Kan. 2009).

[16] *Whitney v. New Mexico*, 113 F.3d 1170, 1173 (10th Cir. 1997) (citation omitted).

[17] *Requena v. Roberts*, 893 F.3d 1195, 1205 (10th Cir. 2018) (quoting *Hall v. Bellmon*, 935 F.2d 1106, 1110 (10th Cir. 1991)).

theory on a plaintiff's behalf."[18] Additionally, a *pro se* litigant is not excused from complying with the rules of the court and is subject to the consequences of noncompliance.[19]

III. Discussion

A. Background Concerning FDA Drug Approval, Off-Label Use, EUAs, and Hydroxychloroquine for the Treatment of COVID-19

The FDA's motion to dismiss for lack of subject matter jurisdiction is brought as a factual attack, as the FDA asks the Court to take judicial notice of its EUA for HCQ for the treatment of COVID-19, the revocation of that EUA, and other relevant documents on the FDA's website. "The court can take judicial notice of information on government websites that is not 'subject to reasonable factual dispute and is capable of determination using sources whose accuracy cannot reasonably be questioned.'"[20] The Court takes judicial notice of these documents and explains certain background information and events underlying the present dispute.

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA must approve a new drug before it may be lawfully sold.[21] "To . . . obtain FDA approval, a new drug must undergo an extensive application and approval process."[22] A manufacturer seeking approval of its product must submit evidence that the product is both safe and effective under the conditions

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[18] *Whitney*, 113 F.3d at 1173–74 (citing *Hall*, 935 F.2d at 1110).

[19] *Ogden v. San Juan Cty.*, 32 F.3d 452, 455 (10th Cir. 1994) (citing *Nielsen v. Price*, 17 F.3d 1276, 1277 (10th Cir. 1994)).

[20] *Goico v. United States Gov't*, No. 20-1025-JWB, 2020 WL 5761438, at *4 n.1 (D. Kan. Sept. 28, 2020) (quoting *New Mexico ex rel. Richardson v. Bureau of Land Mgmt.*, 565 F.3d 683, 702 n.22 (10th Cir. 2009) (citing *Doe v. Heil*, 533 F. App'x 831, 833 n.2 (10th Cir. 2013)).

[21] *See* 21 U.S.C. § 355(a); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973); *Hope Med. Enters., Inc. v. Fagron Compounding Servs.*, LLC, No. 2:19-cv-07748-CAS(PLAx), 2020 WL 3803029, at *2 (C.D. Cal. July 7, 2020).

[22] *Hope Med. Enters., Inc.*, 2020 WL 3803029, at *2 (quoting *Med. Ctr. Pharmacy v. Mukasey*, 536 F.3d 383, 388 (5th Cir. 2008)).

prescribed in the proposed labeling.[23] And when the FDA approves a new drug, it is approving it as safe and effective for the specific conditions of use set forth in the labeling.[24]

However, physicians may exercise their independent medical judgment to prescribe FDA-approved drugs to treat conditions other than those for which the drug is approved, if appropriate for the particular patient.[25]

> Absent state regulation, once a drug has been approved by FDA, doctors may prescribe it for indications and in dosages other than those expressly approved by the FDA. This is a widely employed practice known as "off-label" use. Off-label use does not violate federal law or FDA regulations because the FDA regulates the marketing and distributing of drugs in the United States, not the practice of medicine, which is the exclusive realm of the individual states.[26]

When necessary to respond to "an actual or potential emergency," the FDA may issue an EUA for unapproved drugs, or for unapproved uses of approved drugs, under certain circumstances and for the duration of the emergency, provided that certain statutory criteria are met.[27] Among other criteria, an EUA requires that the drug's known and potential benefits outweigh its known and potential risks.[28] EUAs must be periodically reviewed, and the FDA must revoke or revise an EUA if the statutory criteria are no longer satisfied or public health and safety so require.[29]

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[23] *See* 21 U.SC. § 355(b), (d); *Weinberger*, 412 U.S. at 617.

[24] *See* 21 U.SC. § 355(d).

[25] *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350−51 & n.5 (2001) (citations omitted)*; In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, 678 F.3d 235, 240 (3d Cir. 2012) (first citing *Buckman*, 531 U.S. at 350; then citing *Wash. Legal Found. v. Henney*, 202 F.3d 331, 333 (D.C. Cir. 2000)); *Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006).

[26] *Taft*, 444 F.3d at 505.

[27] 21 U.S.C. § 360bbb-3(a)−(c).

[28] 21 U.S.C. § 360bbb-3(c)(2)(B).

[29] 21 U.S.C. § 360bbb-3(g).

HCQ is approved by the FDA to prevent and treat malaria and to treat lupus erythematosus and rheumatoid arthritis.[30] Although HCQ is not approved to prevent or treat COVID-19, preliminary data at the outset of the pandemic suggested that it might be effective against the virus.[31] On March 28, 2020, the FDA found that HCQ met the statutory criteria and issued an EUA for its use "to facilitate the availability of . . . hydroxychloroquine sulfate during the COVID-19 pandemic to treat patients for whom a clinical trial is not available or participation is not feasible."[32] The EUA applied only to hospitalized patients.[33] Further, the EUA applied only to HCQ supplied from the Strategic National Stockpile ("SNS"),[34] which consists "of drugs, vaccines and other biological products, medical devices, and other supplies . . . to provide for and optimize the emergency health security of the United States."[35] The FDA's EUA issuance letter says nothing about commercial supplies of HCQ.

On June 15, 2020, the FDA revoked its EUA for HCQ distributed from the SNS, finding that the criteria for the EUA's issuance were no longer met.[36] The FDA stated in its EUA Revocation that it had concluded that hydroxychloroquine was not likely effective in treating

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[30] *See* U.S. Food & Drug Admin., Emergency Use Authorization for Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Suppled from the Strategic National Stockpile for Treatment of 2019 Coronavirus Disease 2 (Mar. 28, 2020), https://www.fda.gov/media/136534/download [hereinafter "EUA Issuance"].

[31] *Id*. at 2−3.

[32] *Id*. at 2. Previously, on February 4, 2020, the Secretary of Health and Human Services determined that COVID-19 created "a public health emergency that has a significant potential to affect national security or the health and security of United States citizens living abroad," which is one of the circumstances that permits the issuance of an EUA. 85 Fed. Reg. 18,250-01 (Apr. 1, 2020); *see also* EUA Issuance at 1; 21 U.S.C. § 360bbb-3(b) (setting forth conditions under which the Secretary may declare that circumstances warrant an EUA).

[33] EUA Issuance at 4.

[34] *Id.* at 1, 5−7. The EUA also applied to chloroquine phosphate to be distributed from the SNS. *See id*. at 1.

[35] 42 U.S.C. § 247d-6b(a)(1) (establishing SNS).

[36] U.S. Food & Drug Admin., Letter and Memorandum Revoking Emergency Use Authorization for Use of Chloroquine Phosphate or Hydroxychloroquine Sulfate Suppled from the National Stockpile for Treatment of 2019 Coronavirus Disease 1, 15 (June 15, 2020), https://www.fda.gov/media/138945/download [hereinafter "EUA Revocation"].

COVID-19, and that in light of reports of serious adverse events, the drug's potential benefits did not outweigh its risks.[37] Critically, the FDA's EUA Revocation expressly states that "[w]hile HCQ that has been distributed from SNS is no longer authorized under the EUA . . . to treat hospitalized patients for COVID-19, FDA-approved HCQ can be distributed in interstate commerce."[38] And when announcing the EUA Revocation, the FDA issued a press release stating that "FDA approved products may be prescribed by physicians for off-label uses if they determine it is appropriate for treating their patients, including during COVID."[39]

On July 1, 2020, the FDA published a review of safety issues with the use of HCQ to treat hospitalized patients with COVID-19.[40] In that update, the FDA explained:

> Hydroxychloroquine and chloroquine have not been shown to be safe and effective for treating or preventing COVID-19. They are being studied in clinical trials for COVID-19, and we authorized their temporary use during the COVID-19 pandemic for treatment of the virus in hospitalized patients when clinical trials are not available, or participation is not feasible, through an [EUA]. The medicines being used under the hydroxychloroquine/chloroquine EUA are supplied from the Strategic National Stockpile, the national repository of critical medical supplies to be used during public health emergencies. This safety communication reminds physicians and the public of risk information set out in the hydroxychloroquine and chloroquine healthcare provider fact sheets that were required by the EUA.
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> Hydroxychloroquine and chloroquine can cause abnormal heart rhythms such as QT interval prolongation and a dangerously rapid heart rate called ventricular tachycardia. These risks may increase

[37] *Id*. at 2, 5, 11−12.

[38] *Id*. at 2.

[39] U.S. Food & Drug Admin., FDA News Release, Coronavirus (COVID-19) Update: FDA Revokes Emergency Use Authorization for Chloroquine and Hydroxychloroquine (June 15, 2020), https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-revokes-emergency-use-authorization-chloroquine-and

[40] U.S. Food & Drug Admin., FDA Cautions Against Use of Hydroxychloroquine or Chloroquine for COVID-19 Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems (July 1, 2020), https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or

> when these medicines are combined with other medicines known to prolong the QT interval, including the antibiotic azithromycin, which is also being used in some COVID-19 patients without FDA approval for this condition. Patients who also have other health issues such as heart and kidney disease are likely to be at increased risk of these heart problems when receiving these medicines.[41]

The update provided guidance for physicians treating patients enrolled in clinical trials, and otherwise advised that "[i]f a healthcare professional is considering use of hydroxychloroquine . . . to treat or prevent COVID-19, FDA recommends checking www.clinicaltrials.gov for a suitable clinical trial and consider enrolling the patient. Consider using resources available to assess a patient's risk of QT prolongation and mortality."[42]

B. Standing Principles

Article III of the Constitution gives federal courts the power to exercise jurisdiction only over "Cases" and "Controversies." As the Supreme Court has explained:

> In limiting the judicial power to "Cases" and "Controversies," Article III of the Constitution restricts it to the traditional role of Anglo-American courts, which is to redress or prevent actual or imminently threatened injury to persons caused by private or official violation of law. Except when necessary in the execution of that function, courts have no charter to review and revise legislative and executive action.[43]

One of several doctrines reflecting Article III's case-or-controversy limitation on judicial power is the doctrine of standing.[44] That doctrine requires federal courts, before considering the merits of an action, to "satisfy themselves that 'the plaintiff has "alleged such a personal stake in the

[41] *Id*.

[42] *Id*.

[43] *Summers v. Earth Island Inst*., 555 U.S. 488, 492 (2009) (first citing *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 559–60 (1992); then citing *Los Angeles v. Lyons*, 461 U.S. 95, 111−12 (1983)).

[44] *Id*. at 493.

outcome of the controversy" as to warrant [the plaintiff's] invocation of federal-court jurisdiction.'"[45]

To establish Article III standing, a plaintiff must show: (1) injury in fact, (2) causation, and (3) redressability.[46] To establish the first element, "a plaintiff must show that he or she suffered 'an invasion of a legally protected interest' that is 'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'"[47] "[T]he injury must affect the plaintiff in a personal and individual way."[48] "The 'injury in fact' requirement is satisfied differently depending on whether the plaintiff seeks prospective or retrospective relief."[49] "To seek prospective relief, the plaintiff must be suffering a continuing injury or be under a real and immediate threat of being injured in the future."[50] As to the second element of standing, "there must be a causal connection between the injury and the conduct complained of—the injury has to be 'fairly . . . trace[able] to the challenged action of the defendant, and not . . . th[e] result [of] the independent action of some third party not before the court.'"[51] Finally, as to the third element, "it must be 'likely,' as opposed to merely 'speculative,' that the injury will be 'redressed by a favorable decision.'"[52] At the pleading stage, the plaintiff "must 'clearly . . . allege facts demonstrating' each element" of standing.[53]

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[45] *Id.* (quoting *Warth v. Seldin*, 422 U.S. 490, 498–99 (1975)).

[46] *Lujan*, 504 U.S. at 560–61 (citations omitted).

[47] *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quoting *Lujan*, 504 U.S. at 560).

[48] *Lujan*, 504 U.S. at 560 n.1.

[49] *Tandy v. City of Wichita*, 380 F.3d 1277, 1283 (10th Cir. 2004) (citing *City of Los Angeles v. Lyons*, 461 U.S. 95, 101–02, 105 (1983)).

[50] *Id*. (citing *Lyons*, 461 U.S. at 101−02, 107 n.8).

[51] *Lujan*, 504 U.S. at 560 (alteration in original) (quoting *Simon v. E. Ky. Welfare Rights Org.*, 426 U.S. 26, 41–42 (1976)).

[52] *Id*. at 561. (quoting *Simon*, 426 U.S. at 38, 43).

[53] *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547 (2016) (quoting *Warth v. Seldin*, 422 U.S. 490, 518 (1975)).

C. Goico Lacks Standing and this Case Must Therefore Be Dismissed

The FDA argues that Plaintiff lacks standing to sue because he has suffered no injury in fact, let alone an injury traceable to the FDA, and because his alleged injury would not be redressed by the injunctive relief he seeks. The Court agrees that Plaintiff has failed to allege facts demonstrating standing.

Assuming only for the sake of argument that Plaintiff has adequately alleged an injury-in-fact due to his inability to obtain HCQ, he still cannot establish the remaining two standing requirements—causation and redressability—because the FDA is not withholding HCQ or preventing physicians from prescribing it as he alleges. Some of Plaintiff's arguments are set forth in his proposed sur-reply and in his pleading titled "Rebuttal Evidence."[54] Although these are improper pleadings, the Court will exercise its discretion to grant Plaintiff leave to file his sur-reply, the sur-reply will be deemed filed as of the date of this Order, and the Court will consider both pleadings here in the interests of judicial efficiency and finality.[55] The Court nonetheless finds Plaintiff's arguments unavailing.

First, Plaintiff cannot establish the causation element of standing. As explained above, while the FDA has revoked the EUA for HCQ supplied from the SNS, HCQ remains an FDA-approved drug, is commercially available, and may be prescribed off-label where deemed appropriate by a physician in his or her independent medical judgment. As recently explained by another court when denying injunctive relief similar to that requested here:

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[54] Docs. 32-1, 33.

[55] "Under D. Kan. Rule 7.1(c), briefing on motions is limited to the motion (with memorandum in support), a response, and a reply. Surreplies are not typically allowed." *COPE v. Kan. State Bd. of Educ.*, 71 F. Supp. 3d 1233, 1238 (D. Kan. 2014) (citation omitted). "Leave to file a surreply is generally only granted in 'rare circumstances' such as where the movant 'improperly raises new arguments in a reply.'" *Sheldon v. Vermonty*, No. 98-2277-JWL, 2000 WL 33911222, at *3 (D. Kan. Sept. 27, 2000) (quoting *Pehr v. Rubbermaid, Inc.,* 87 F. Supp. 2d 1222, 1236 (D. Kan. 2000)), *aff'd*, 269 F.3d 1202 (10th Cir. 2001); *see also COPE*, 71 F. Supp. 3d at 1238.

> Hydroxychloroquine is commercially available, and physicians are free to prescribe the drug for off-label uses absent any direction to the contrary by state medical authorities. Nothing in the EUA, or its revocation, had any direct impact on the availability of hydroxychloroquine in the commercial market.[56]

The independent decision of a third-party medical professional not to prescribe HCQ is not fairly traceable to the FDA.[57]

Plaintiff ultimately acknowledges the fact that HCQ can be legally prescribed for off-label use,[58] but alleges that the multiple doctors he has consulted will not prescribe the drug for him because they deem it unsafe based on the FDA's statements and/or because they fear sanctions from state medical authorities. However, Plaintiff's own evidence is unhelpful to his argument that physicians are precluded from prescribing HCQ for the treatment of COVID-19 by either the FDA or state authorities.

Plaintiff's "Rebuttal Evidence" pleading consists of an email Plaintiff received from a research analyst at the Kansas Legislative Research Department outlining statements by various state medical authorities on best practices during COVID-19.[59] The gist of these statements is that while "there is no prohibition on legal 'off-label' prescribing," drug-therapy decisions should be evidence-based and comply with the standard of care.[60] While some states may be imposing certain restrictions on the use of HCQ to prevent or treat COVID-19, Plaintiff offers no

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[56] *Assoc. of Am. Physicians & Surgeons v. FDA*, No. 1:20-CV-493, 2020 WL 5742698, at *1 (W.D. Mich. Aug. 14, 2020); *see also Assoc. of Am. Physicians & Surgeons v. FDA*, No. 20-1784, 2020 WL 5745974, at *2 (6th Cir. Sept. 24, 2020) (stating that the FDA "[has] not interfered with [physicians'] ability to prescribe or obtain commercially available HCQ").

[57] *Assoc. of Am. Physicians & Surgeons*, 2020 WL 5742698, at *6 (stating that "[w]hen a plaintiff's injury is the result of 'the independent action of some third party not before the court,' the plaintiff generally lacks standing to seek its redress.'") (alteration in original) (quoting *Crawford v. U.S. Dep't of Treasury*, 868 F.3d 438, 455 (6th Cir. 2017))).

[58] Doc. 26 at 4.

[59] Doc. 33.

[60] *Id*. at 4.

evidence that Kansas is one of them beyond a statement by the Kansas Board of Pharmacy "encourag[ing] vigilance in processing new prescriptions for . . . hydroxychloroquine and recommend[ing] reaching out to prescribers to verify diagnosis."[61] Nowhere does Plaintiff support that state authorities are preventing Kansas doctors from prescribing HCQ against "their own free will," as he asserts.[62]

Even if Plaintiff offered evidence that Kansas medical authorities have restricted or forbidden the use of HCQ for off-label use, those actions would not be fairly traceable to the FDA, nor does the agency wield authority over state regulators who might discipline physicians for prescribing HCQ because the regulation of medical practice is generally within the states' exclusive authority.[63] Protecting the public health by assuring drug safety is an integral part of the FDA's mission.[64] The fact that the FDA has warned healthcare providers and the public of some potential risks of HCQ—and that some state authorities may have restricted the use of the drug or some physicians may have chosen not to prescribe it for the treatment of COVID-19 because of those risks when weighed against the drug's potential benefits—does not establish the causal link necessary to confer standing on Plaintiff here.

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[61] *Id*. at 3.

[62] *Id*. at 1.

[63] *See, e.g., Planned Parenthood Cincinnati Region v. Taft*, 444 F.3d 502, 505 (6th Cir. 2006); *Assoc. of Am. Physicians & Surgeons v. FDA*, No. 20-1784, 2020 WL 5745974, at *2 (6th Cir. Sept. 24, 2020) (stating that "state medical boards—not [the FDA]—control how physicians can prescribe or use drugs," and that the FDA "cannot be held responsible for the allegedly threatening regulatory environment surrounding [HCQ's] use"); *Assoc. of Am. Physicians & Surgeons v. FDA*, No. 1:20-CV-493, 2020 WL 5742698, at *8 (W.D. Mich. Aug. 14, 2020) ("[Plaintiff's contentions illustrate that its members['] grievances lie against the state authorities, not the federal defendants here. Any traceability from the potential and speculative complained of injury . . . is too indirect and cut off by independent actors making independent decisions.").

[64] U.S. Food & Drug Admin., FDA Fundamentals, https://www.fda.gov/about-fda/fda-basics/fda-fundamentals (last accessed Nov. 30, 2020).

Plaintiff also argues that the FDA has caused HCQ to be in short supply by "hoarding" it in the SNS.[65] Not only does this statement about HCQ scarcity appear to be false as of the date of this Order,[66] Plaintiff does not allege in his Complaint that physicians are *unable* to prescribe him HCQ due to a shortage; rather, he alleges that they are *unwilling* to prescribe him the drug. Nor does he allege that he was or is a person who would have been eligible for treatment with HCQ under the EUA. Plaintiff has simply failed to allege a causal connection between his injury and the FDA's conduct sufficient to establish standing.

Second, Plaintiff has failed to satisfy the redressability element of standing because he cannot show that it is likely rather than speculative that his injury would be redressed by a decision in his favor. In his Complaint, Plaintiff requests that the Court enjoin the FDA from disallowing HCQ for prophylactic use and enjoin any medical authority from punishing any doctor who prescribes HCQ. As discussed above, the FDA is not disallowing the use of HCQ, nor does the FDA have anything to do with the state's regulation of medical practice. The unspecified "medical authorities" to which Plaintiff refers are not parties to this action and the Court therefore has "no power to adjudicate a personal claim or obligation" against them.[67]

In his response to the FDA's motion to dismiss, Plaintiff appears to alter his request for injunctive relief by asking that that Court order the FDA to release HCQ from the SNS. This change in tactic fails because, among other reasons, even if the Court were to order the release of

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[65] Doc. 26 at 2, 5.

[66] U.S. Food & Drug Admin., Current and Resolved Drug Shortages & Discontinuations Reported to FDA, https://www.accessdata.fda.gov/scripts/drugshortages/dsp_ActiveIngredientDetails.cfm?AI=Hydroxychloroquine%20Sulfate%20Tablets&st=r (last accessed November 30, 2020) (showing that shortage of HCQ sulfate tablets from March to June 2020 has been resolved and that product is currently "available").

[67] *Zenith Radio Corp. v. Hazeltine Rsch., Inc.*, 395 U.S. 100, 110 (1969) (citation omitted); *see also Thomas v. Bolls*, No. 18-cv-00692-GPG, 2018 WL 9489245, at *2 (D. Colo. May 16, 2018) (stating that "the Court cannot issue an order against individuals who are not parties to a pending lawsuit") (citation omitted)).

HCQ from the SNS, Plaintiff would still need a prescription to obtain it. Again, Plaintiff does not allege in his Complaint and has not established that HCQ scarcity is the reason why his physician will not prescribe him the drug, which is currently available in the commercial market, such that an order from this Court would redress his injury.

Plaintiff lacks standing sufficient to invoke federal jurisdiction because he has shown neither a causal connection between his injury and the FDA's conduct, nor that an order from this Court granting him the relief he seeks would redress his injury. This case must be dismissed for lack of jurisdiction.

IV. Conclusion

Although this case is only a little over two months old, Plaintiff has filed more than ten motions or other pleadings seeking action from the Court and/or reiterating or adding to arguments previously made. Plaintiff filed several of these pleadings after the Court ordered the parties to submit no further briefing on the FDA's motion to dismiss. Further, it appears that this action is one of five cases that Plaintiff has filed in the District of Kansas since March 2019—in each case, Plaintiff sought a preliminary injunction against the state or federal government, and all of the cases have now been dismissed.[68] In one of Plaintiff's prior cases, Judge Thomas Marten took note of Plaintiff's "vexatious" approach to litigation, imposed certain filing restrictions, and cautioned him that "the court may impose further filing restriction as appropriate."[69]

[68] *See Goico v. Kansas*, No. 19-1055-JTM, 2019 WL 2160812, at *2 (D. Kan. May 17, 2019) (dismissing case as frivolous pursuant to 28 U.SC. § 1915(e)(2)(B) and § 1915A(b)(1)); *Goico v. Kansas*, No. 19-1284-CM-GEB, 2020 WL 68375, at *1 (D. Kan. Jan. 7, 2020) (dismissing action for lack of subject matter jurisdiction); *Goico v. Kansas*, No. 20-CV-01026-EFM-KGG, 2020 WL 3034814, at *2−3 (D. Kan. June 5, 2020) (dismissing case for lack of jurisdiction and standing); *Goico v. U.S. Gov't*, No. 20-1025-JWB, 2020 WL 5761438, at *3−4 (D. Kan. Sept. 28, 2020) (dismissing case for lack of standing).

[69] *See Goico v. Kansas*, 2019 WL 2160812, at *2−3.

This Court is deeply sympathetic to, and does not intend to in any way minimize, the stress and isolation Plaintiff is experiencing as a result of the COVID-19 virus. However, Plaintiff is cautioned to be mindful of the limited time and resources the Court has available to respond to repeated filings reiterating the same arguments and requesting the same relief. While this case did not reach the point at which the Court felt it necessary to impose formal filing restrictions, Plaintiff could face such restrictions in future cases if his current approach to litigation persists.

IT IS THEREFORE ORDERED BY THE COURT that Plaintiff's Motion for Permission to File a Rebuttal (Sur-Reply or Sur-Response) to [the FDA's] Reply Memorandum in Support of Defendants' Motion to Dismiss (Doc. 32) is **granted**. Plaintiff's sur-reply is deemed filed and has been considered by the Court in this Order. The FDA's Motion to Dismiss for Lack of Subject Matter Jurisdiction and Failure to State a Claim upon which Relief Can Be Granted (Doc. 22) is **granted** and this case is **dismissed.**

IT IS FURTHER ORDERED that Plaintiff's Motion to Join this Case with Case 20-1025 (Doc. 3), Emergency Motion for Preliminary Injunction (Doc. 4), Motion to Rebut (Doc. 20), Emergency Motion to Expedite Ruling on Defendant's Motion (Doc. 29), and Urgent Emergency Motion for Emergency TRO (Doc. 30) are **denied as moot.**

IT IS SO ORDERED.

Dated: December 3, 2020

S/ Julie A. Robinson
JULIE A. ROBINSON
UNITED STATES DISTRICT JUDGE